DETAILED ACTION

Status of the application

1. The previous Office Action sent on 01/24/2008 was not the version intended for mailing and was inadvertently sent to Applicant. Consequently, that version is vacated and the correct version of the Final rejection is set forth herein.

Status of the claims

2. In the amendment filed on 11/26/2007, Applicant cancelled claims 1-7 and 10-21, amended claims 8 and 9, and added the new claims 22-24. Consequently, the claims 8-9 and 22-24 are pending and under examination.

Withdrawn claim rejections

Claim Rejections - 35 USC § 112

3. The enablement rejection of claims 8 and 9 under 35 USC § 112 1st paragraph, as well as the indefiniteness rejection of the claims 8 and 9 under 35 USC § 112 2nd paragraph are withdrawn in view of the amended claims.

Maintained and new claim rejections necessitated by amendment

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8-9 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because they do not refer back to the preamble. Moreover, it is unclear which are the practical steps to be taken when determining whether the test compound tested earlier in the method inhibits mesangial cell growth. It is also unclear if the amino acid sequence which is 95% homologous to Seq. Id. No. : 1 still maintains the requirement of binding the lysophosphatidic ligand.

The claim 9 is an incomplete kit claim since it does not designate the components of the kit and the relationship between them. Therefore, the metes and bounds of the claim are unclear.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. There are no method steps disclosed that are to be taken to determine if the test compound identified in the previous method is useful for treating the conditions claimed. As presented, the claim is just a mental step and not a method claim.

6. The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 9 remain rejected and claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (U.S. Pat. 6, 485,922, 11/26/2002). As iterated in the previous Office action, Erickson et al. teach a method for identifying compounds which modulate the activity of any of the EDG receptors, comprising the steps of exposing a compound and LPA to the EDG-2 receptor coupled to a response pathway, under conditions and for a time sufficient to allow interaction of LPA with the EDG-2 receptor and an associated response through the pathway, and b) detecting an increase or a decrease in the stimulation of the response pathway, relative to the absence of the tested compound (col. 6 from line 28 to col. 7, line 42). The Seq. Id. of the receptor mentioned by Erickson et al, Seq. Id No: 20, is identical to Seq. Id. No.: 1 of the instant application. Since the detection of any activation of the EDG-2 receptor is necessarily linked to the binding of the LPA to the EDG-2 receptor, the limitations of the claim 8 and 9 is present in Erickson et al. Moreover, the intended use of the binding altering drugs thus uncovered is not a precondition of the method so that the claims of the instant Application are anticipated by Erickson et al.

On page 12 of the Remarks Applicants argue that Erickson et al. does not teach or suggest a test that identifies a compound that inhibits mesangial cell growth.

The arguments were carefully considered but not found persuasive because the test performed by Erickson et al. would identify compounds that modulate the activity of EDG receptors. Unless the Applicant presents experimental evidence that the EDG-2 receptor found on mesangial cells is different than the EDG-2 receptor known in the art and claimed by Erickson et al., a difference that is nowhere presented in the Specification, the claimed method is no different than the method of Erickson et al. Inhibiting proliferation of mesangial cells by antagonistic action of a compound binding to EDG-2 receptor is linked to signal transduction events which occur in all cells expressing the receptor and is not unique to mesangial cells. Also, the step d) of the method of screening is not considered an actual method step since it is just a mental step and is not given patentable weight. Therefore the method of screening of Erickson et al. would necessarily anticipate the method of screening of the instant Application. With respect to the kit claims (9 and 23), the reagents that are claimed as a part of kit would inherently meet the limitations.

Claims 8 and 9 remain rejected and claims 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (U.S. Pat. 6,875,757 04/05/2005).

As presented in the Office Action of 07/29/2007, Miller et al. teach method of modulating LPA activity on an LPA receptor which includes providing a compound of the present invention which has activity as an LPA receptor antagonist and contacting an LPA receptor with the compound under conditions effective to inhibit LPA-induced

activity of the LPA receptor (col. 8, lines 10-40). One of the LPA receptors is EDG-2 (fig. 1). Again, any LPA activity through EDG-2 is in the wake of LPA binding to the EDG-2 receptor and thus the limitation existent in the claims of the instant Application is met.

On page 14 of the Remarks Applicants argue that Miller et al. does not teach or suggest a test that inhibits mesangial cell growth. Inhibiting proliferation of mesangial cells by antagonistic action of a compound binding to EDG-2 receptor is linked to signal transduction events which occur in all cells expressing the receptor and is not unique to mesangial cells. Therefore the method of screening of Miller et al. would necessarily anticipate the method of screening of the instant

The arguments were carefully considered but not found persuasive because the test performed by Miller et al. would identify compounds that modulate the activity of LPA receptors. Also, the step d) of the method of screening is not considered an actual method step since it is just a mental step and is not given patentable weight. With respect to the kit claim (9 and 23), the reagents that are claimed as a part of kit would inherently meet the limitations. Unless the Applicant presents experimental evidence that the LPA receptor found on mesangial cells is different than the LPA receptor (EDG-2 receptor) taught by claimed by Miller et al., difference that is nowhere presented in the specification, the claimed method is no different than the method of Miller et al. while the intended use of the compound is not given patentable weight

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/ Ph.D.

Primary Examiner, Art Unit 1647